



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

HF-35  
Public Health Service T2094M

Food and Drug Administration  
New Orleans District  
Southeast Region  
4298 Elysian Fields Avenue  
New Orleans, Louisiana 70122-3896

Telephone: 504-589-6341  
Fax: 504-589-6360

October 1, 1998

**WARNING LETTER NO. 99-NOL-01**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Mr. Joseph S. McNulty, III  
President  
Ambulatory Equipment Services  
Post Office Box 428  
Magee, Mississippi 30111-0428

Dear Mr. McNulty:

During the July 20-21, 1998, inspection of your manufacturing facility, our investigator documented deviations from the Current Good Manufacturing Practices regulations. These deviations cause your drug product, U.S.P. Oxygen, to be adulterated within the meaning of section 502(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). The controls used for the manufacture, processing, packing or holding of this product are not in conformance with Current Good Manufacturing Practice regulations (Title 21 Code of Federal Regulations, Parts 210 and 211).

Our inspection revealed the following CGMP deficiencies: failure to properly calibrate the Oxygen analyzer used in performing oxygen identity tests, and to document that the testing is performed.

The above identification of violations is not intended to be an all inclusive list of deficiencies. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to properly correct them may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 days of the receipt of this letter, of the steps that you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Nicole F. Hardin, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122, telephone number 504-589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Ms. Hardin.

Sincerely,

A handwritten signature in black ink, appearing to read "James E. Gamet".

James E. Gamet  
District Director  
New Orleans District

Enclosure: FDA 483